



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

January 13, 2023

Re: Animal Welfare Assurance  
A3823-01 [OLAW Case 10Q]

Dr. Mary Dickinson  
Senior Vice President and Dean of Research  
Baylor College of Medicine- Houston  
One Baylor Plaza, MS BCM335  
Houston, TX 77030

Dear Dr. Dickinson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 11, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Baylor College of Medicine. According to the information provided, OLAW understands that five mice were given expired ketamine as part of a euthanasia cocktail. No adverse events occurred due to use of the expired agent.

The corrective actions consisted of retraining the laboratory staff and having the staff review relevant institutional policies.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



## OFFICE OF RESEARCH

One Baylor Plaza, BCM310  
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## CONFIDENTIAL

January 11, 2023

Brent Morse, DVM, DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
olawdco@mail.nih.gov

RE: Assurance #D16-00475

Dear Dr. Morse,

As Institutional Official for Baylor College of Medicine (BCM), I have the duty to inform you of our Institutional Animal Care and Use Committee's (IACUC) recent findings in animal research after an assessment of the following protocol:

**Protocol:** AN-7988: Light Response of Retinal Ganglion Cells in Normal and Genetically Modified Mice

**Species:** Mice

**Funding Sources:** National Institutes of Health (NIH): R01-EY034223 and Non-PHS Funding

For this investigator's first incident of this nature, the IACUC determined that the following finding constituted *serious noncompliance*<sup>1</sup> with the federal regulations:

*9/28/2022 – Animals were given an expired drug*<sup>ii</sup>

During a semi -annual inspection, the laboratory drug logs were reviewed and expired Ketamine was used to make a Ketamine/Xylazine cocktail which was given to five mice for euthanasia. There were no concerns with the effectiveness of the drug cocktail and a secondary method of euthanasia was performed on the animals.

*12/13/2022 – Determination at a fully convened IACUC meeting*

To protect the welfare of animals and prevent future recurrence, the IACUC required following corrective actions:

1. All research personnel are required to complete the following AALAS modules: Guide for the Care and Use of Laboratory Animals and Working with Controlled Substances
2. All research personnel are required to complete the interactive course "Top 10 Pitfalls in Animal Research and How to Avoid Them" training.
3. All research personnel are required to review the policy "Guidelines for Use of Pharmaceutical and Non Pharmaceutical Grade Drugs Chemical and Other Substances."

This finding of non-compliance does not appear to pose any potential or actual effect on costs related to this PHS-supported research.

<sup>1</sup> PHS Policy IV.F.3.a: "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a. any serious or continuing noncompliance with this Policy;"

<sup>ii</sup> PHS Policy IV.C.1.b: "Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justification for scientific reasons in writing by the investigator."

This notification will also be sent to AAALAC International, the National Institutes of Health and the non-PHS funding source according to the terms and conditions of the award.

Please do not hesitate to contact me if you have any questions.

Sincerely,

(b) (6)

Mary Dickinson, PhD  
Sr. Vice President and Dean of Research  
Institutional Official  
Baylor College of Medicine

cc: Principal Investigator  
Department Chair  
Research Compliance Services files

**McCoy, Devora (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, January 12, 2023 7:37 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Reports- Assurance D16-00475

Good morning (b) (6)

Thank you for sending us these two reports and we will send official responses soon.

Best,  
Devora

Devora McCoy, BS, MBA  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

**From:** (b) (6)  
**Sent:** Wednesday, January 11, 2023 4:45 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] OLAW Reports- Assurance D16-00475

Dear Dr. Morse,

Please find the attached notifications of research non-compliance as determined by our IACUC, and sent on behalf of Dr. Mary Dickinson, Institutional Official.

Please feel free to contact me if you have any questions.

Thank you,

(b) (6)

